EXHIBIT C.3

K131158
Page 1 of 4

SECTION 5: 510(k) SUMMARY

510(k) Summary

Date Prepared: July 16, 2013

AUG 2 1 2013

Submitter:
Marrek, Inc.
3293 Niblick Drive
Park City, UT 84098
Phone: 1 (512) 582-2453
Facsimile: 1 (713) 589-7964

Contact:
Jeremy M. Fotheringham, President & CEO
Mobile: 1 (801) 870-4323

Trade/Proprietary Name of Device: CORVIEW

Common Name of Device: System, Image Processing, Radiological

Classification: Class II per 21 CFR 892.2050, Picture archiving and communications system, Product Code LLZ

Legally Marketed Predicate Device:

1. 2D Cardiac Performance Analysis MR 1.0 device (K120135), manufactured by TomTec Imaging Systems
2. Virtue (CORE Module) (K111833), manufactured by Diagnosoft, Inc.

Description of New CORVIEW Device:

CORVIEW is an independent software solution for the segmentation and quantitative analysis of digitized cardiac magnetic resonance images (MRIs). CORVIEW operates on higher-end off-the-shelf PC or Apple computers and is compatible with Cardiac MRI digital images in DICOM format from a range of commercial MRI machine vendors. The CORVIEW software platform is also designed to process MRIs received from various modes of image exchange.

CORVIEW presents a state-of-the-art method to process and quantify the extent of left atrial enhancement (LAE) within the left atrial wall by contouring and identifying the endo- and epi-cardial borders from contrast enhanced MR image sequences that have been acquired as part of a conventional cardiac MRI examination.

CORVIEW is designed for the processing of 3D image datasets allowing users to produce contour models and visualizations of left atrial structure and contrast enhancement. Based on 3D-acquired datasets, a feature classification algorithm supports the calculation of LAE. From these corresponding algorithms, total percentage of enhancement can be derived. In addition, the corresponding shape of the left atrium can also be obtained.

Indications for Use of the New Device:

Indications for Use:

The Corview software application is indicated for viewing and post-processing of cardiovascular magnetic resonance images (MRIs) to obtain Left Atrial Enhancement (LAE) quantification and visualization on a 3D model. It provides measurements of LAE within the left atrial wall.

It enables:

- Importing Cardiac MRIs in DICOM format
- Qualitative analysis of the cardiac MRIs using display functionality such as panning, windowing, zooming, and navigation through series/slices and phases
- Quantitative measurement in cardiac MRIs, specifically LAE

It is intended for use by qualified medical professionals experienced in examining and evaluating cardiovascular MRIs, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process.

The target population of Corview is not restricted. However image acquisition by an MRI scanner with cardiac capability may limit the use of the device for certain sectors of the general public.

Corview is intended to view only cardiac magnetic resonance images acquired from an MRI scanner with cardiac capabilities.

The CORVIEW software application is intended for use in the clinical setting.

Comparison of the Technological Features of the New Device and Predicate Devices:

The new CORVIEW device, the lawfully marketed predicate Tom Tec Imaging Systems 2D Cardiac Performance Analysis MR 1.0 device (K120135), and the Diagnosoft Virtue-CORE device (K111833) are all stand-alone software

applications using cardiac data obtained from standard magnetic resonance images. Features of CORVIEW are comparable to those of the predicate devices. The main differences include:

1. The new CORVIEW quantifies the amount of contrast enhancement within the left atrial wall. The predicate Tom Tec Imaging Systems 2-D Cardiac Performance Analysis MR 1.0 device quantifies the myocardial deformation and movement of the entire heart muscle.
2. The new CORVIEW constructs and visualizes a 3D model of the left atrium.
3. The new CORVIEW quantifies the amount of contrast enhancement within the left atrial wall. The predicate Diagnosoft Virtue – CORE device quantifies the amount of contrast enhancement within the right and left ventricles as well as the surrounding vessels.

Testing:

Non-Clinical Performance Data Testing:

Software testing and validation were done at the code and system level according to written test protocols established before testing was conducted.

The test procedure was performed and documented. The test results were reviewed by designated technical professionals to ensure acceptability criteria were satisfied prior to the release of the software.

The results are summarized in the test summary report. The conclusion states that:

- Verification strategies and test procedures used are appropriate
- Software system test procedures trace to software requirements
- All software requirements are tested or otherwise verified
- Test results meet the required pass/fail criteria

Adverse Effects on Health:

The potential risks are identified in a risk management analysis and report and are controlled by the software development team, risk management processes, documented verification and validation processes to ensure performance to specifications, Federal Regulations, user requirements, and adherence to industry and international standards.

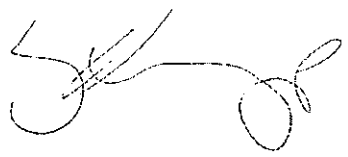
Risk analysis aspects were treated in the risk management report. Based on this document, the applied methods in the literature and the techniques of the product (which are considered in the risk analysis) were evaluated. No further risks were identified.

K131158
Page 4 of 4

Conclusion:

The conclusions drawn from the specifications and performance testing of the new CORVIEW device demonstrate that the new CORVIEW device is at least as safe and as effective and performs as well as or better than the predicate TomTec Imaging Systems 2D Cardiac Performance Analysis MR 1.0 device, (K120135) and the Diagnosoft Virtue – CORE device (K111833). For these reasons, we believe the new CORVIEW device is substantially equivalent to the predicate devices.

Signed,



Jeremy M. Fotheringham
President & CEO
Marrek, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 21, 2013

Marrek, Inc.
% Mr. Jeremy M. Fotheringham
President & CEO
3293 Niblick Drive
PARK CITY UT 84098

Re: K131158
Trade/Device Name: Corview
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 16, 2013
Received: August 19, 2013

Dear Mr. Fotheringham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131158

Device Name: Corview

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) ___K131158___